U.S. Patent Application No. 10/743,739 Attorney Ref. No.: 037003-0307368

# AMENDMENT OF THE CLAIMS

#### 1-46. (Cancelled)

- 47. (Currently amended) A method for enhancing an antigen-specific cytotoxic T cell lymphocyte response against cervical cancer cells in a patient in need thereof, comprising administering:
  - (a) an antigen-containing adjuvant formulation, the formulation comprising a human papillomavirus E7 protein that is capable of inducing a cytotoxic T cell lymphocyte response specific for the human papillomavirus E7 protein; and
  - (b) a therapeutically effective amount of at least one agent that is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of transforming growth factor-β (TGFβ) selected from the group consisting of an anti-TGFβ antibody, a TGFβ receptor-fusion protein, a TGFβ receptor Fc-fusion protein, an anti-TGFβ receptor antibody that blocks the interaction of TGFβ and TGFβ receptor, and a thrombospondin peptide that binds to TGFβ and inhibits TGFβ activity: wherein the combination of the antigencontaining adjuvant formulation and the at least one agent elicits a synergized cytotoxic T cell lymphocyte response against cervical cancer cells in a patient.

### 48-50. (Cancelled)

- 51. (Previously presented) The method of claim 47, wherein the antigen-containing adjuvant formulation and at least one agent of step (b) are administered sequentially or concurrently, and in any order.
- 52. (Previously presented) The method of claim 47, wherein the antigen-containing adjuvant formulation is a microfluidized antigen formulation comprising:
  - (i) a stabilizing detergent,
  - (ii) a micelle-forming agent, and
  - (iii) a biodegradable and biocompatible oil,

U.S. Patent Application No. 10/743,739 Attorney Ref. No.: 037003-0307368

said antigen formulation being formulated as a stable oil-in-water emulsion.

- 53. (Previously presented) The method of claim 52, wherein the detergent is provided in an amount ranging from approximately 0.05 to 0.5%.
- 54. (Previously presented) The method of claim 53, wherein the amount of detergent is about 0.2%.
- 55. (Previously presented) The method of claim 52, wherein the detergent is selected from the group consisting of sorbitan-mono-9-octadecenoate-poly(oxy)-l,2-ethanediyl, polyoxyethylene sorbitan monopalmitate, polyoxyethylene sorbitan monopalmitate, polyoxyethylene sorbitan monostearate, N-dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, alkyl (C<sub>9</sub>-C<sub>12</sub>) sodium sulfates, and sorbitan trioleate.
- 56. (Previously presented) The method of claim 52, wherein the micelle-forming agent has a hydrophile-lipophile balance of between 0 and 2.
- (Previously presented) The method of claim 52, wherein the amount of the micelle-forming agent ranges from 0.5 to 10%.
- (Previously presented) The method of claim 57, wherein the amount of the micelle-forming agent ranges from 1.25 to 5%.
- 59. (Previously presented) The method of claim 52, wherein the amount of oil ranges from 1 to 10%.
- 60. (Previously presented) The method of claim 59, wherein the amount of oil ranges from 2.5 to 5%.
- (Previously presented) The method of claim 52, wherein the oil exhibits a melting temperature of less than 65°C.

U.S. Patent Application No. 10/743,739 Attorney Ref. No.: 037003-0307368

- (Previously presented) The method of claim 52, wherein the oil is selected from the group consisting of squalane, eicosane, tetratetracontane, pristane, and vegetable oils.
- 63. (Previously presented) The method of claim 52, wherein the antigen formulation comprises sorbitan-mono-9-octadecenoate-poly(oxy)-l,2-ethanediyl, a block copolymer having the structure:

$$\begin{array}{c} HO(CH_2CH_2O)_{a^{-}}(CHCH_2O)b\text{-}(CH_2CH_2O)_{a}H,\\ & |\\ CH_3 \end{array}$$

wherein a and b are such that the average molecular weight of the polyoxypropylene blocks in the molecule is 4000 and approximately 10% of the molecular weight of the copolymer is composed of the polyoxyethylene blocks, and squalane.

## 64. (Cancelled)

 (Previously presented) The method of claim 52, wherein the antigen formulation lacks an immunostimulating muramyl dipeptide.

## 66-67. (Cancelled)

68. (Previously presented) The method of claim 52, wherein the antigen-containing adjuvant formulation and at least one agent of step (b) are administered sequentially or concurrently, and in any order.